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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,115	11/01/2003	Warren L. Starkebaum	P-9930.01	8923
27581	7590	02/17/2006		
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			EXAMINER BERHANU, ETSUB D	
			ART UNIT 3735	PAPER NUMBER

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/698,115	STARKEBAUM, WARREN L.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Etsub D. Berhanu	3735	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/14/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: element 56, Figure 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. The use of the trademarks SynchroMed and Medtronic Inc. have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Objections***

3. Claims 16 and 22 are objected to because of the following informalities: Claim 16 should read "at least one of gastric electrical activity and transabdominal impedance", and claim 22 is unclear when it states "memory means to data." Appropriate correction is required.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6, 8, 9, 11-17, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Clegg et al.'808 (US Patent No. 4,823,808).

Clegg et al.'808 teaches a method for control of obesity, overweight and eating disorders comprising: sensing physiological parameters in the esophageal and/or gastrointestinal tract, wherein the physiological parameters include gastric pressure from distention, pH changes from secretions, temperature changes from food or liquid, and hunger sensations from smooth muscle activity (col. 2, lines 45-54); measuring a characteristic of a physiological parameter such as the intensity of a stomach acid concentration (pH measurement); generating a communication to the patient as a function of the measurement of the sensed physiological parameter wherein the communication comprises transmitting a wireless communication to an external module (col. 5, lines 22-32).

Clegg et al.'808 also teaches a system comprising: a sensor to sense physiological parameters of a patient that change as a function of activity of a stomach of the patient, said physiological parameters as mentioned above wherein a chemical sensor is used to measure stomach acid concentration (pH) and the presence or absence of selected chemicals (col. 5, lines 24-25), a mechanical sensor is used to measure distention of the stomach, an electrical sensor is used to measure hunger sensations from smooth muscle activity, and a temperature sensor is used to measure temperature changes from food or liquid (col. 2, lines 50-54); a processor to generate a communication to the patient as a function of the sensed

physiological parameter and a module to wirelessly transmit the communication to an external module (col. 4, lines 3-27).

Regarding claims 23 and 24, Clegg et al.'808 teaches a computer-readable medium that causes a processor to sense a physiological parameter of a patient and generate a communication to the patient as a function of the sensed physiological parameter (col. 3, lines 44-49 and col. 4, lines 3-16), and causes a processor to measure a characteristic of a physiological parameter and generate a communication to the patient as a function of the measurement (col. 3, lines 54-68 and col. 4, lines 1-2).

6. Claims 8, and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Foley et al.'780.

Foley et al.'780 teaches a system comprising: an implantable sensor and processor, wherein the sensor is used to monitor gastric electrical activity and the processor is used to generate a communication to the patient as a function of the sensed physiological parameter (page 3, sections [0038-0039]); communication means to notify a patient of the communication (page 3, section [0061]); the processing means are configured to measure a characteristic of the physiological parameter (page 4, section [0067]) and the characteristic is compared to a threshold (page 5, section [0077]); the processing means comprise a memory means to data associated with the sensed physiological parameter and the measured characteristic (page 5, section [0073]).

#### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clegg et al.'808, as applied to claims 1 and 8 above, further in view of Barreras et al.'061 (US Patent No. 4,556,061).

Clegg et al.'808 teaches all the elements of the current invention, as discussed in paragraph 5, except for an implanted alert module.

Barreras et al.'061 teaches an alternate sound generator implanted in a patient, which vibrates to alert the patient of a problem (col. 4, lines 6-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the implanted vibrator of Barreras et al.'061 for the telemetry and external sound generator of Clegg et al.'808, as it is generally held to be within the skill of the art to substitute alternate equivalent expedients.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clegg et al.'808, as applied to claim 3 above, further in view of Bourgeois'994 (US Patent No. 5,836,994).

Clegg et al.'808 teaches all the elements of the current invention, as discussed in paragraph 5, except for a method further comprising measuring a second characteristic of a second physiological parameter as a function of a first characteristic of a first physiological parameter.

Bourgeois'994 teaches a method of using two sensors to detect normal peristaltic contractions, whereby one sensor measures low frequency gastrointestinal electrical activity and a second sensor senses

intrinsic gastrointestinal electrical activity, wherein the second sensor only senses after slow waves have been sensed by the first sensor (col. 2, lines 10-21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Clegg et al.'808 to measure the intrinsic gastrointestinal electrical activity of a patient as a function of the low frequency gastrointestinal electrical activity of the patient, since this method allows the detection of normal peristaltic contractions.

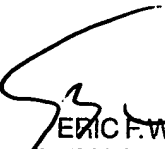
### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571.272.4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDB

  
ERIC F. WINAKUR  
PRIMARY EXAMINER